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Group Art Unit: 1616
Applicants' Response to Paper No. 8

REMARKS

Claims 10-30 are currently pending in the present application.

In Paper No. 8, the Examiner indicates that claims 10-20 are allowed and that claims 27 and 28, while objected to as being dependent upon a rejected base claim, would be allowable if rewritten in independent form. (*See,* Paper No. 8, ¶¶ 6 & 8). Additionally, in Paper No. 8, the Examiner withdraws the rejection of claims 10-30 under 35 U.S.C. §112, first paragraph, and also the rejection of claims 10-20 under 35 U.S.C. §103(a) over Okamoto, Y., "Synthesis of Alkyl Dihydrogenphosphate by the Reaction of Alcohols and Silyl Polyphosphate", BULL. CHEM. SOC. JPN., vol. 58, pp.3393-4 (1985), in view of Cremlyn, R., *et al.*, "Some Steroid Phosphates and Related Compounds", J. CHEM. SOC., vol. 17, pp. 2305-10 (1969) (hereinafter referred to as "Cremlyn") and Ramirez, F., *et al.*, "Synthesis of Steroid Phosphates via Monomeric Metaphosphate", J. ORG. CHEM., vol. 48, pp.1417-20 (1983) (hereinafter referred to as "Ramirez").

However, in Paper No. 8, the Examiner maintains the rejections of claims 21 and 22 under 35 U.S.C. §102(b), as being anticipated by Cremlyn or Ramirez. Specifically, the Examiner has contended that Cremlyn discloses ergosteryl dihydrogen phosphate and lanosteryl dihydrogen phosphate, citing lines 18 and 27 of the 2nd column of page 2309. With respect to Ramirez, the Examiner has contended that the reference discloses stigmasterol dihydrogen phosphate and ergosteryl dihydrogen phosphate, citing compounds 5 and 6 of page 1419. The Examiner argues that the disclosure of these compounds anticipates the rejected claims. The Examiner further contends that Applicants' arguments set forth in Applicants' Request for Reconsideration filed on February 14, 2003, are not persuasive as they "center[] around the processes taught by the prior art . . .." (*See,* Paper No. 8, ¶ 3). The Examiner goes on to note that the patentability of a product-by-process claim is based upon the product, not the process. The Examiner then concludes that the claimed compounds must encompass the prior art despite the differences in the processes used to make each. (*See, id.*).

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Applicants strenuously, but respectfully, traverse each of the Examiner's two rejections for anticipation and the arguments and contentions in support thereof for the reasons set forth below in detail.

In order for a rejection under 35 U.S.C. §102(b) to be proper, each and every element of the claimed invention must be taught, either expressly or inherently, in a single prior art reference. (*See, e.g.*, M.P.E.P. §2131). In addition, as the Examiner has pointed out, the patentability of a product-by process claim is determined based upon the product itself. As the M.P.E.P. states, ". . . If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (*See*, M.P.E.P., 8th Ed. §2113, *citing In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)). However, it is important to also note that the Federal Circuit has also held that an Examiner must provide a rationale showing that the claimed product is the same or similar to that of the prior art, even though it is produced by a different process. (*See*, M.P.E.P., 8th Ed. §2113, *citing In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)). Once such a rationale has been provided, only then does the burden shift to the applicant to come forward with rebuttal evidence. (*See, id.*).

Applicants submit that the Examiner has failed to set forth the required rationale showing that the claimed product is the same or similar to that of the prior art. On the contrary, using somewhat circular logic, the Examiner argues, "[t]herefore, the compounds recited by the instant claims encompass the sterol phosphates taught by the prior art eventhough, different processes made the prior art compounds . . ." because "[t]he patentability of a product does not depend on its method of production." (Paper No. 8, ¶ 3). Essentially, the Examiner is arguing that the claimed product and the prior art products are the same or similar because the Examiner says they are. This argument falls well short of providing the required rationale.

Applicants respectfully submit that the claimed product is in fact different than the prior art products. Moreover, these differences are not solely in the processes used to make each product. However, the differences in the processes used to make each product help to highlight the differences in the end products themselves.

Cremlyn discloses the production of various sterol compounds, including certain sterol dihydrogen phosphates, via the *hydrolysis* of the corresponding sterol phosphoro-dichloridates. (*See*, Cremlyn, p. 2305, 2nd col., lines 14-24). Cremlyn specifically discloses the simultaneous production of the corresponding steryl chloride as a result of such hydrolysis, and suggests a mechanism for their formation. (*See, id.*, at lines 27-31). Specifically, Cremlyn states that, "[t]he cholesteryl chloride *formed in these hydrolyses* probably arises, in the main, from intermolecular S_N2 attack by the evolved hydrogen chloride . . .." (*See, id.* (*emphasis added*)). Thus, the products disclosed by Cremlyn contain steryl chloride compounds.

Applicants' claimed sterol phosphates are the products of processes which do not employ phosphorodichloridates, and accordingly, do not contain sterol chlorides resulting from their preparation. In other words, Applicants' claimed compounds are different than the products disclosed by Cremlyn. Applicants recognize that patentability does not depend on the process used to make the product. However, Applicants submit that the process, as set forth in the rejected claims, *results* in a different product than that which is disclosed in the prior art as containing the by-product steryl chloride. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) over Cremlyn.

Ramirez discloses a process for preparing sterol phosphates wherein a source of metaphosphate is reacted with a sterol. Ramirez discloses the use of (1-phenyl-1,2-dibromoethyl)phosphonic acid only, because of its ready availability and its convenient rate of decomposition in aprotic solvents such as dichloromethane. (*See*, Ramirez, p. 1418, "Results and Discussion"). Ramirez discloses a specific synthetic route for the preparation of steroid dihydrogen phosphates wherein (1-phenyl-1,2-dibromoethyl)phosphonic acid is reacted with the dried steroid in a solution of anhydrous dichloromethane. In the disclosed synthetic procedure, Ramirez specifically points out the presence of unwanted α-bromostyrene by-product in the phosphate product. (*See, id.*, at pp. 1419-20).

Applicants' claimed sterol phosphates are the products of processes which do not employ (1-phenyl-1,2-dibromoethyl)phosphonic acid, and accordingly, do not contain brominated by-products resulting from their preparation. Again, Applicants submit that the

process, as set forth in the rejected claims, *results* in a different product than that which is disclosed in the prior art as containing the brominated by-products. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) over Ramirez.

Finally, in Paper No. 8, the Examiner rejects claims 23-26, 29 and 30 under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 5,958,433 of Simonnet (hereinafter referred to as "Simonnet"), in view of U.S. Pat. No. 6,051,250 of Ribier, *et al.* (hereinafter referred to as "Ribier"). Specifically, the Examiner contends that Simonnet discloses a stable dispersion containing a lipid vesicle which comprises a lamellar phase formed of at least one silicone surfactant, and that it is "advantageous to add an ionic amphiphilic lipid such as the alkali metal salts of cholesterol phosphate because it enhances the stability of the dispersion . . .." (*See,* Paper No. 8, ¶ 5). The Examiner also contends that Ribier discloses a cosmetic composition which contains a dispersion of vesicles formed from a lipid-phase membrane containing at least one ionic and/or nonionic amphiphilic lipid, such as cholesterol acid phosphate, encapsulating an aqueous phase.

The Examiner argues that it would have been obvious to "the skilled artisan", at the time the invention was made, to have incorporated cholesterol acid phosphate into cosmetic compositions because Simonnet discloses that ionic amphiphilic lipids provide stability to dispersions. On this basis, the Examiner argues that the claimed invention is obvious.

Applicants respectfully traverse the Examiner's rejection, and the arguments and contentions in support thereof, for the following reasons.

It is well-settled that where a combination of references is used to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of

success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

One embodiment of Applicants' claimed invention is directed to a cosmetic preparation comprising a formulation base and a sterol phosphate of the general formula (I). Another embodiment of Applicants' claimed invention is directed to a method of deodorizing the human body by applying an effective amount of such a cosmetic composition. Yet another embodiment of Applicants' claimed invention is directed to a method of enhancing the deodorizing effects of a cosmetic preparation by combining an effective amount of a sterol phosphate of the general formula (I) with a cosmetic preparation containing at least one deodorizing agent.

Simonnet discloses a dispersion containing vesicles which comprise a lamellar phase made from at least one silicone surfactant. (*See*, Simonnet, claim 1). An ionic amphiphilic lipid may be incorporated INTO the lamellar phase to prevent flocculation of the vesicles. (*See*, Simonnet, claim 11). Among the ionic amphiphilic lipids which can be incorporated INTO the lamellar phase are alkali metal salts of dicetyl- and dimyristylphosphate; alkali metal salts of cholesterol sulphate; alkali metal salts of cholesterol phosphate; lipoamino acids such as mono- and disodium acylglutamates; sodium salts of phosphatidic acid; phospholipids; and alkylsulphonic derivatives of the formula disclosed therein in which R represents C_{16}-C_{22} alkyl, preferably $C_{16}H_{33}$ or $C_{18}H_{37}$, or a mixture thereof, and M is an alkali metal such as sodium and potassium; and mixtures thereof. (*See*, Simonnet, col. 3, lines 33-52).

The lamellar phase of the vesicles disclosed in Simonnet represents a lipid bilayer into which such an amphiphilic lipid may be incorporated. Simonnet does not teach or suggest the addition of a sterol phosphate to an already formed cosmetic formulation base. The dispersion disclosed by Simonnet contains these vesicles which are essentially spherical lipid bilayers encapsulating an internal phase. Within the lipid bilayer, an amphiphilic lipid may be incorporated. The amphiphilic lipid is not combined with a formulation base as claimed.

According to the teachings of Simonnet, the only reason one of ordinary skill in the art would be motivated to incorporate an amphiphilic lipid into a composition would be if

that composition contained lamellar based lipid vesicles which could be stabilized by the incorporation of such an additional lipid. Moreover, Simonnet provides no motivation towards the selection of cholesterol phosphates over any other amphiphilic lipids. Accordingly, one of ordinary skill in the art would find no motivation to combine an already prepared cosmetic formulation base and a sterol phosphate to produce a cosmetic preparation as claimed.

Ribier fails to remedy the deficiencies of Simonnet. In much the same manner, Ribier is directed to vesicles formed by lamellar lipid bilayers, into which stabilizing agents may be incorporated. This does not provide one of ordinary skill in the art with either a teaching or suggestion, nor any motivation, to prepare a cosmetic composition by combining a formulation base and a sterol phosphate.

None of the cited references teaches or suggests the combination of a formulation base and a sterol phosphate. Moreover, there is no teaching or suggestion in any of the cited references which would motivate one of ordinary skill in the art to modify the teachings of the references to include an amphiphilic lipid outside of a lamellar lipid bilayer comprising a silicone surfactant. Absent any teaching or suggestion of each and every element, and given that there is no motivation to modify the references to arrive at the claimed invention, it cannot reasonably be argued that one of ordinary skill in the art would expect to successfully achieve the claimed invention.

Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness based on the cited references, as none of the three criteria necessary to establish such a *prima facie* case of obviousness has been satisfied. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of the claims under 35 U.S.C. §103(a).

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance are respectfully requested.

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Respectfully submitted,

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(Date)

By: _____

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